315.010 Definitions for chapter.

As used in this chapter, unless the context requires otherwise:

(1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, or ingestion, whether topically or by any other means;

(2) "Association" means the Kentucky Pharmacists Association;

(3) "Board" means the Kentucky Board of Pharmacy;

(4) "Collaborative care agreement" means a written agreement between a specifically identified individual practitioner and a pharmacist who is specifically identified, whereby the practitioner outlines a plan of cooperative management of a specifically identified individual patient's drug-related health care needs that fall within the practitioner's statutory scope of practice. The agreement shall be limited to specification of the drug-related regimen to be provided and any tests which may be necessarily incident to its provisions; stipulated conditions for initiating, continuing, or discontinuing drug therapy; directions concerning the monitoring of drug therapy and stipulated conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;

(5) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients. Compounding, as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists;

(6) "Confidential information" means information which is accessed or maintained by a

pharmacist in a patient's record, or communicated to a patient as part of patient counseling, whether it is preserved on paper, microfilm, magnetic media, electronic media, or any other form;

(7) "Continuing education unit" means ten (10) contact hours of board approved continuing pharmacy education. A "contact hour" means fifty (50) continuous minutes without a break period;

(8) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription drug in a suitable container, appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;

(9) "Drug" means any of the following:

(a) Articles recognized as drugs or drug products in any official compendium or supplement thereto; or

(b) Articles, other than food, intended to affect the structure or function of the body of man or other animals; or

(c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or

(d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

(10) "Drug regimen review" means retrospective, concurrent, and prospective review by a pharmacist of a patient's drug-related history, including but not limited to, the following areas:

(a) Evaluation of prescription drug orders and patient records for:

1. Known allergies;

2. Rational therapy contraindications;

3. Appropriate dose and route of administration;

4. Appropriate directions for use; or

5. Duplicative therapies.

(b) Evaluation of prescription drug orders and patient records for drug-drug, drugfood, drug-disease, and drug-clinical laboratory interactions;

(c) Evaluation of prescription drug orders and patient records for adverse drug reactions; or

(d) Evaluation of prescription drug orders and patient records for proper utilization and optimal therapeutic outcomes;

(11) "Immediate supervision" means under the physical and visual supervision of a pharmacist;

(12) "Incidental" as used in KRS 315.0351(1) means dispensing fewer than twenty-five (25) prescriptions in a calendar month;

(13) "Manufacturer" means any person engaged in the manufacture of drugs or devices; [~~, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container~~];

(14) "Medical order" means a lawful order of a specifically-identified practitioner for a specifically-identified patient for the patient's health care needs. "Medical order" may or may not include a prescription drug order;

(15) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government;

(16) “Normal Distribution Channel” means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, the manufacturer’s co-licensee, the manufacturer’s third-party logistics provider, or the manufacturer’s exclusive distributor to:

(a) a wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(b) a wholesale distributor to a chain pharmacy warehouse to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(c) a chain pharmacy warehouse to that chain pharmacy warehouse’s intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(d) as prescribed by the Board’s regulations.

(17) “Pedigree” means a statement or record in a written form or electronic form, approved by the Board that records each wholesale distribution of any given prescription

drug (excluding veterinary prescription drugs). The pedigree shall minimally include the following information for each transaction:

(a) the source of the prescription drug, including the name and principal address of the seller;

(b) the proprietary and established name of the prescription drug, the amount of the prescription drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(c) the business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;

(d) information that states that the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased; and

(e) a certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury.

(18 [~~16~~]) "Pharmacist" means a natural person licensed by this state to engage in the practice

of the profession of pharmacy;

(19 [~~17~~]) "Pharmacist intern" means a natural person who is:

(a) Currently certified by the board to engage in the practice of pharmacy under

the direction of a licensed pharmacist and who satisfactorily progresses

toward meeting the requirements for licensure as a pharmacist;

(b) A graduate of an approved college or school of pharmacy or a graduate who

has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) A qualified applicant awaiting examination for licensure as a pharmacist or the results of an examination for licensure as a pharmacist; or

(d) An individual participating in a residency or fellowship program approved by the board for internship credit;

(20 [~~18~~]) "Pharmacy" means every place where:

(a) Drugs are dispensed under the direction of a pharmacist;

(b) Prescription drug orders are compounded under the direction of a pharmacist; or

(c) A registered pharmacist maintains patient records and other information for the purpose of engaging in the practice of pharmacy, whether or not prescription drug orders are being dispensed;

(21 [~~19~~]) "Pharmacy technician" means a natural person who works under the immediate supervision, or general supervision if otherwise provided for by statute or administrative regulation, of a pharmacist for the purpose of assisting a pharmacist with the practice of pharmacy;

(22 [~~20~~]) "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the

course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;

(23 [~~21~~]) "Practitioner" has the same meaning given in KRS 217.015(35);

(24 [~~22~~]) "Prescription drug" means a drug which:

(a) Under federal law is required to be labeled with either of the following statements:

1. "Caution: Federal law prohibits dispensing without prescription"; or

2. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or

(b) Is required by any applicable federal or state law or administrative regulation to be dispensed only pursuant to a prescription drug order or is restricted to use by practitioners;

(25 [~~23~~]) "Prescription drug order" means an original or new order from a practitioner for drugs, drug-related devices or treatment for a human or animal, including orders issued through collaborative care agreements. Lawful prescriptions result from a valid practitioner-patient relationship, are intended to address a legitimate medical need, and fall within the prescribing practitioner's scope of professional practice;

(26 [~~24~~]) "Pharmacy-related primary care" means the pharmacists' activities in patient

education, health promotion, assistance in the selection and use of over-the-counter drugs and appliances for the treatment of common diseases and injuries as well as those other activities falling within their statutory scope of practice;

(27 [~~25~~]) "Society" means the Kentucky Society of Health-Systems Pharmacists;

(28 [~~26~~]) "Supervision" means the presence of a pharmacist on the premises to which a pharmacy permit is issued, who is responsible, in whole or in part, for the professional activities occurring in the pharmacy; [~~and~~]

29 "Wholesale Distributor" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds five percent (5%) of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period. Wholesale distribution does not include:

(a) the sale, purchase, or trade of a prescription drug or device, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of a prescription drug or device pursuant to a prescription;

(b) the sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons;

(c) intracompany transactions, unless in violation of own use provisions;

(d) the sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(e) the sale, purchase, or trade of a prescription drug or device or the offer to sell, purchase, or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(f) the purchase or other acquisition by a hospital, pharmacy, or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals, pharmacies or similar health care entities that are members of these organizations;

(g) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(h) the sale, purchase, or trade of blood and blood components intended for transfusion;

(i) the return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, or charitable institution in accordance with the board's regulations; or

(j) the sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's regulations.

(30 [~~27~~]) "Wholesale Distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the Commonwealth, including but not limited to manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy

warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. [~~"Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.~~]

315.036 License [~~Permit~~] to be acquired by wholesale distributor; Board authority to regulate wholesale distributors [~~manufacturer or wholesaler -- Exceptions -- Fee -- Records required -- Report~~].

(1) Each wholesale distributor that provides services in the Commonwealth, whether the wholesale distributor is located within the Commonwealth or out side the Commonwealth, shall be licensed by the board and shall renew the license using an application provided by the Board. [~~Except as provided in subsection (4) of this section, each manufacturer or wholesaler of drugs shall be required to register with and obtain a permit from the board.~~] Such license [~~permit~~] shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars ($250) annually or increase more than twenty-five dollars ($25) per year.

(2) Effective July 1, 2007, wholesale distributors shall be required to maintain a pedigree for each prescription drug that is wholesale distributed outside the normal distribution channel, in accordance with policy and procedure set by the board. [~~Manufacturers and wholesalers shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that manufacturers and wholesalers periodically report to the board all drugs manufactured, received, and sold.~~]

(3) The board shall set a date when pedigrees shall electronically record for all prescription drugs, each wholesale distribution starting with the sale by a manufacturer

through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. Consideration must be given, however, to the large scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed. [~~Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.~~]

(4) The board shall promulgate rules to establish standards and requirements for the issuance and maintenance of a wholesale distributor license. [~~The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice:~~

~~(a) Compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order;~~

~~(b) Distributes limited quantities of prescription drugs to practitioners or pharmacies for the purpose of alleviating temporary shortages or responding to emergencies;~~

~~(c) Distributes prescription drugs to practitioners or pharmacies for the purpose of supplying or replenishing reasonable quantities utilized by practitioners or pharmacies in the normal course of professional practice, if:~~

~~1. A record of the transfer is maintained by both the transferring pharmacy and the receiving practitioner or pharmacy for a period of no less than five (5) years;~~

~~2. The transfer is documented by purchase order or invoice and no prescription drug order shall be used to obtain supplies of drugs under this subsection;~~

~~3. The total number of units transferred during a twelve (12) month period shall not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and~~

~~4. All distributions are in accordance with all applicable federal and state laws and administrative regulations; or~~

~~(d) Transfers prescription drug inventory from one pharmacy to another pharmacy to effect a permanent pharmacy closure.~~]

(5) The board shall have the authority to recognize a third party to inspect and accredit wholesale distributors.

(6) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three (3) years.

(7) Subject to the Federal Food, Drug and Cosmetic Act and all applicable federal law and regulation, an FDA approved manufacturer, including its affiliates, subsidiaries, agents and other entities under common ownership and control of the manufacturer, that exclusively distributes its own FDA approved prescription drug or biologic product, and that has not left the manufacturer's chain of custody shall be exempt from the licensing

requirements of this Chapter. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

Alternative #1

NEW SECTION:

315.0361 Prescription Drug Deception

(1) A Person who, with intent to defraud or deceive, performs the act of Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device commits a felony of the third degree;

(2) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to deliver to another Person a complete and accurate Pedigree, when required, concerning a Prescription Drug prior to transferring the Prescription Drug to another Person commits a felony of the third degree;

(3) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to acquire, complete and accurate Pedigree, when required, concerning a Prescription Drug prior to obtaining the Prescription Drug from another Person commits a felony of the third degree;

(4) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly destroys, alters, conceals, or fails to maintain complete and accurate Pedigree concerning any Prescription Drug in his possession commits a felony of the third degree;

(5) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who is in possession of a Pedigree, as required by the Board, and who knowingly fails to Authenticate the Pedigree as required, and who nevertheless Wholesale Distributes or

attempts to further Wholesale Distribute Prescription Drug(s) commits a felony of the third degree;

(6) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, falsely swears or certifies that he has Authenticated any documents related to the Wholesale Distribution of Prescription Drugs, commits a felony of the third degree;

(7) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly forges, Counterfeits, or falsely creates any Pedigree, who falsely represents any factual matter contained on any Pedigree, or who knowingly omits to record material information required to be recorded in a Pedigree, commits a felony of the third degree;

(8) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly purchases or receives Prescription Drug(s) or Device(s) from a Person, not legally authorized to Wholesale Distribute Prescription Drug(s) or Device(s), in Wholesale Distribution commits a felony of the third degree;

(9) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly sells, barters, brokers, or transfers Prescription Drug(s) or Device(s) to a Person not legally authorized to purchase Prescription Drug(s) or Device(s), under the jurisdiction in which the Person receives the Prescription Drug(s) or Device(s) in a Wholesale Distribution, commits a felony of the third degree;

(10) A Person who knowingly possesses, actually or constructively, any amount of a Contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a Contraband Drug(s) or Device(s) commits a felony of the third degree;

(11) A Person who knowingly forges, Counterfeits, or falsely creates any Label for a Prescription Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Prescription Drug(s) or Device(s) commits a felony of the third degree;

(12) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the Commonwealth, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), commits a felony of the third degree; and

(13) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the Commonwealth, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), and whose acts result in the death of a Person, commits a felony in the first degree.

(14) A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall be ordered to forfeit to the Commonwealth any real or Personal property:

(1) Used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(2) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the Board and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution that led to the conviction.

Alternative #2

NEW SECTION:

315.0361 Criminal Penalties

(1) Unknowing Violations - If a person engages in the wholesale distribution of prescription drugs in violation of this Act, the person may be imprisoned for not more than 15 years, and fined not more than $50,000, or both.

(2) Knowing Violations - If a person knowingly engages in wholesale distribution of prescription drugs in violation of this Act, the person shall be imprisoned for any term of years, or fined not more than $500,000, or both.